

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION**

This document relates to:
*The County of Summit, Ohio, et al. v. Purdue
Pharma L.P., et al.*
Case No. 18-op-45090

and

*The County of Cuyahoga v. Purdue Pharma
L.P., et al.*
Case No. 1:18-op-45004

MDL No. 2804

Hon. Judge Dan A. Polster

**MEMORANDUM IN SUPPORT OF
DISTRIBUTOR-DEFENDANTS' MOTION
FOR SUMMARY JUDGMENT ON CIVIL CONSPIRACY CLAIM**

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INTRODUCTION

The thrust of Plaintiffs’ Complaints—now fully embraced by Plaintiffs’ liability experts—is that Manufacturers of opioids engaged in a “massive false marketing campaign to drastically expand the market” for opioid medications.¹ That campaign, Plaintiffs allege, tainted virtually every source doctors could rely on for information. It changed the treatment guidelines relied on by doctors, including guidelines issued by numerous professional associations and the Federation of State Medical Boards. The DEA endorsed the Federation’s guidelines—guidelines that advised that “opioids were ‘essential’ for treatment of chronic pain, including as a first prescription option”²—as “consistent” with the DEA’s own position on pain treatment. In recognition of this position, the DEA increased the production quotas for prescription opioids 39-fold between 1995 and 2015.

As a result, according to Plaintiffs’ experts, doctors prescribed more opioids; pharmacy-benefit managers approved the drugs for their formularies; pharmacies dispensed more opioids; and both private and public insurers paid for the increased volume. All this was possible, Plaintiffs further allege, because Manufacturers concealed their marketing scheme from the public by, among other things, “secretly control[ling] messaging.”³

Plaintiffs seek to impose liability on Distributors for Manufacturers’ alleged marketing misconduct based on civil conspiracy. Distributors are middlemen, however, and they played no role in establishing the standard of care for prescribing opioids. The discovery record now establishes that there is a total failure of evidence regarding Distributors’ supposed involvement in the alleged marketing conspiracy. There is no evidence that Distributors agreed to, or did, participate in Manufacturers’ alleged false-marketing scheme. Nor is there any evidence that

¹ Cuyahoga TAC ¶¶ 1, 821; Summit TAC ¶¶ 1, 775. “Manufacturers” refers to the named defendant pharmaceutical manufacturers, also referred to by Plaintiffs as the “Marketing Defendants.”

² Cuyahoga TAC ¶ 362; Summit TAC ¶ 374.

³ Cuyahoga TAC ¶ 818; Summit TAC ¶ 772.

Distributors agreed, or tried, to influence DEA's decisions to increase opioid production quotas, or agreed with one another not to report suspicious opioid orders. The complete lack of evidence that Distributors agreed with one another (or anyone else) to achieve an unlawful objective is fatal to the civil conspiracy claim.

Therefore, regardless of whether Plaintiffs have raised triable issues of fact as to Distributors' liability for their own conduct on other claims, the Court should grant summary judgment as to Distributors on the civil conspiracy claim (Cuyahoga Count 11 and Summit Count 11).

THE RELEVANT UNDISPUTED FACTS

The moving parties⁴ are wholesale distributors of pharmaceutical products who do not develop, test, or prescribe any drugs, including opioids. They purchase pharmaceutical products from manufacturers and fill wholesale orders submitted by their state-licensed customers, typically pharmacies.⁵ Those customers, in turn, dispense drugs to patients, pursuant to medical providers' prescriptions that Distributors never see, and which, according to Plaintiffs' experts, were overwhelmingly written pursuant to the then-prevailing standard of care.⁶

By federal statute, the United States Attorney General is authorized to determine what amount of controlled substances (including opioids) may be manufactured each year. 21 U.S.C. § 826. The Attorney General has delegated that authority to the Drug Enforcement Administration ("DEA"), which must set the annual production quota based on the legitimate

⁴ Cardinal Health, Inc., McKesson Corp., AmerisourceBergen Drug Corp., Anda, Inc., H.D. Smith, H.D. Smith, LLC f/k/a H.D. Smith Wholesale Drug Company, H.D. Smith Holdings, LLC, H.D. Smith Holding Company, Prescription Supply Inc., Henry Schein, Inc., and Henry Schein Medical Systems, Inc.

⁵ See Ex. I.12 (Norris Tr.) at 42:18–43:4; Ex. I.4 (Cavacini Tr.) at 267:11–15; Ex. I.21 (Zimmerman Tr. (Aug. 3, 2018)) at 42:8–43:4, 43:21–451.

⁶ See Ex. III.3 (Lembke Rep.) at 12 ("[O]pioid overprescribing is not the result of a small subset of so-called 'pill mill' doctors, ... but rather has been driven by a wholesale shift in medical practice."); see also Ex. III.2 (Keyes Rep.) at 18 ("'Pill Mills' do not explain in any significant way the expansion of opioid prescribing and opioid-related harm in the US."); Ex. III.4 (Parran Rep.) ¶ 296 ("[W]hile significant, the pill mills were not responsible for the wide scale exposure of the population to the drugs. The epidemic we see today did not arise just out of pill mills or 'bad doctors.'").

medical need for the particular drug. 21 CFR § 1303.11(a). From 1993 to 2015, DEA authorized a 39-fold increase of the manufacturing quotas for oxycodone, with quotas for other prescription opioids also seeing large increases.⁷ The record evidence confirms that Distributors play no role in setting, advocating for, or increasing quotas.⁸

Under federal law, Distributors are required to design and operate a system to detect suspicious orders of controlled substances, including opioids, and to report those orders to the relevant DEA field office when detected. 21 CFR § 1301.74(b). Each Distributor had (and has) such a system.⁹ There is no record evidence that Distributors entered into any agreement—either among themselves or with Manufacturers—not to report suspicious orders. To the contrary, the record reflects that Distributors reported thousands of suspicious orders during the period relevant to this case.¹⁰ Similarly, Distributors declined to do business with, or have terminated business relationships with, hundreds of pharmacies whose conduct with respect to controlled substances raised concern.¹¹ And while Distributors reported suspicious orders they received, there is no evidence that any of them had any ability to see—let alone monitor and report—suspicious orders that were placed with other Distributors. But even if individual Distributors may be faulted for not reporting suspicious orders in some instances, there is no evidence that there was an agreement not to report.

⁷ See Ex. II.3 (CAH_MDL2804_00084164—Letter from Senators Richard Durbin, et al. to Chuck Rosenberg, Acting Adm’r, DEA (July 11, 2017)); Ex. II.7 (PAR_OPIOID_MDL_0000386240—Drug Enforcement Agency, Aggregate Production Quota History for Selected Substances 2003–2013 (Oct. 2, 2012)).

⁸ See, e.g., Ex. I.9 (Harper-Avila Tr.) at 111:12–18; 112:9–12; 112:21–113:1.

⁹ See e.g. Ex. I.12 (Norris Tr.) at 66:7–13, 244:21–245:1; Ex. I.19 (Walker Tr.) at 361:16–21; 381:2–7; Ex. I.21 (Zimmerman Tr. (Aug. 3, 2018)) at 111:12–112:17, 258:20–259:21; Ex. I.6 (Patrick Cochrane Tr.) at 19:5–21:2; Ex. I.5 (Michael Cochrane Tr.) at 287:20–288:20.

¹⁰ See Ex. I.15 (Quintero Tr.) at 124:14–18; Ex. I.2 (Boggs Tr. (Jan. 17, 2019)) at 362:6–11; *see also* ECF.#412 and accompanying data (transmission of DEA’s suspicious order reports for six states to the Court).

¹¹ See Ex. I.15 (Quintero Tr.) at 126:17–127:5, 223:6–17; Ex. I.2 (Boggs Tr. (Jan. 17, 2019)) at 380:3–12; Ex. II.1 (ABDCMDL00337006 (“Do Not Ship” list)); Ex. I.3 (Robert Brown Tr.) at 221:5–17, 223:3–226:16; Ex. II.2 (Anda Opioids_MDL_0000543135–36); Ex. I.8 (George Euson Tr.) at 170:14–171:5.

There also is no evidence that Distributors were involved in Manufacturers’ alleged marketing scheme—no evidence that Distributors played any role in conceiving the scheme, were ever invited to join it, or had any role in implementing or concealing it. There is no evidence that Distributors knew, or had a basis to know, whether the misrepresentations allegedly made by Manufacturers (and persons allegedly acting secretly on their behalf) about the risks and benefits of opioids were, as Plaintiffs allege, without a scientific basis and false or misleading. While Distributors at times offered pharmaceutical manufacturers certain opportunities to include information about their products in communications to pharmacies and other parties, there is no record evidence that Distributors created the contents of these communications. And of primary significance, there is no evidence that any of these communications contained the misrepresentations regarding the risks and benefits of opioids about which Plaintiffs complain. Rather, as Plaintiffs’ marketing expert conceded, the communications typically provided information only about price, availability, and other matters of primary interest to pharmacies and other buyers.¹²

ARGUMENT

The Complaints allege that Distributors conspired with Manufacturers to (1) increase DEA production quotas and, more generally, to lobby the government to weaken regulations, and (2) further Manufacturers’ deceptive marketing scheme.¹³ The Complaints also allege that Distributors conspired with one another not to report suspicious orders.¹⁴ No record evidence supports these allegations. Part I addresses the law of civil conspiracy, and Parts II, III, and IV address the absence of evidence to support any of Plaintiffs’ conspiracy theories and allegations.

¹² See Ex. I.13 (Perri Tr.) at 218:17-219:6 (the “vast majority” of ads hosted by Distributors concerned “information about ... price and product availability” only).

¹³ Cuyahoga TAC ¶¶ 532–533; Summit TAC ¶¶ 549–550.

¹⁴ Cuyahoga TAC ¶¶ 534–536; Summit TAC ¶ 551–553.

I. THE LAW OF CIVIL CONSPIRACY REQUIRES PROOF, *INTER ALIA*, OF AN AGREEMENT AND AN ILLEGAL OBJECTIVE

The elements of a civil conspiracy claim under Ohio law are: “(1) a malicious combination, (2) involving two or more persons, (3) causing injury to person or property, and (4) the existence of an unlawful act independent from the conspiracy itself.” *Cianfaglione v. Lake Nat’l Bank*, ___ N.E.3d ___, 2019 WL 1517667, *4 (Ohio Ct. App. Apr. 8, 2019) (internal quotation marks omitted); *see also Hale v. Enerco Grp., Inc.*, 2011 WL 49545, at *5 (N.D. Ohio Jan. 5, 2011) (Polster, J.) (citing *Universal Coach, Inc. v. New York City Transit Auth., Inc.*, 90 Ohio App.3d 284, 629 N.E.2d 28, 33 (Ohio Ct. App. 1993)). Malice is defined as “that state of mind under which a person does a wrongful act purposely, without a reasonable or lawful excuse, to the injury of another.” *Williams v. Aetna Fin. Co.*, 700 N.E.2d 859, 868 (Ohio 1998) (internal quotation marks omitted); *see also Berridge v. McNamee*, 66 N.E.3d 1266, 1279 (Ohio Ct. App. 2016) (same). Essential to a civil conspiracy claim is proof of “an agreement or understanding” among the alleged conspirators. *FV I Inc. v. Goodspeed*, 974 N.E.2d 664, 677 (Ohio Ct. App. 2012).

Ohio courts have scrupulously enforced the requirement that the plaintiff prove ***an agreement*** to achieve an unlawful objective. This is so even if the alleged agreement is a “tacit” one. *See, e.g., Woodward Const., Inc. v. For 1031 Summit Woods, LLC*, 30 N.E.3d 237, 243 (Ohio Ct. App. 2015) (a plaintiff seeking to prove a civil conspiracy “must at least show a common understanding or design, even if tacit, to commit an unlawful act.” (internal quotation marks omitted)). Demonstrating that no conspiracy liability can be imposed without proof of an agreement, courts applying Ohio law emphasize the “qualitative difference” between conspiracy and aiding and abetting and, thus, have declined to impose liability for conspiracy even when there is evidence the defendant knew of and facilitated the principal wrongdoer’s conduct. *See Aetna Cas. & Sur. Co. v. Leahey Constr. Co., Inc.*, 219 F.3d 519, 538–39 (6th Cir. 2000)

(reversing civil conspiracy judgment; “the degree of involvement required for civil conspiracy is higher than for civil aiding and abetting,” because “conspiracy focuses on whether the defendant agreed to join in the wrongful conduct” (internal quotation marks omitted)). Where the evidence is “as consistent with independent conduct as it [is] with a conspiracy,” a claim fails. *Hensley v. Gassman*, 693 F.3d 681, 695 (6th Cir. 2012) (affirming the grant of summary judgment for defendant on § 1983 conspiracy); *see also Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 768 (1984) (to prove an agreement, the evidence must “tend[] to exclude the possibility of independent action”).¹⁵

Consistent with these principles of substantive Ohio law, the Sixth Circuit demands *evidence* supporting conspiracy allegations to withstand summary judgment. *Robertson v. Lucas*, 753 F.3d 606, 622 (6th Cir. 2014) (affirming summary judgment for defendant because plaintiffs “failed to produce any *specific evidence* that the defendants shared a single plan and a common objective”);¹⁶ *Bergin Fin. Inc. v. First Am. Title Co.*, 397 F. App’x 119, 127 (6th Cir. 2010) (affirming summary judgment for defendant because, even though circumstantial evidence may be used to establish the agreement at issue, “none of the evidence even inferentially supports [defendant’s] involvement in a civil conspiracy”).

II. PLAINTIFFS’ CLAIMS THAT DISTRIBUTORS CONSPIRED TO LOBBY THE GOVERNMENT FAIL AS A MATTER OF LAW.

Plaintiffs allege that Distributors conspired with Manufacturers to “increase[e] the [opioid production] quotas set by the DEA,”¹⁷ and “through their lobbying efforts ... collectively

¹⁵ At the motion to dismiss stage, this Court suggested that a “general conspiratorial objective of expanding the opioid market” could support a conspiracy claim (ECF #1203, at 22). There is no record evidence that Distributors conspired with Manufacturers to “expand[] the opioid market.” In any case, expanding the market for a legal product is not an unlawful objective. Similarly, “[t]aking[] advantage of the industry structure,” ECF #1203 at 22, does not show any agreement to achieve an unlawful objective.

¹⁶ Unless otherwise noted, all emphases are added.

¹⁷ Cuyahoga TAC ¶ 898.

sought to undermine the impact of the [Controlled Substances Act].”¹⁸ In other words, Plaintiffs (county governments) seek to impose civil liability on Distributors for allegedly engaging in protected political advocacy because they disagree with the policies that Distributors allegedly advocated. That claim fails at the threshold as a matter of law. The law is clear that lobbying the government is constitutionally protected activity under the First Amendment and cannot form the basis of a civil conspiracy claim. As to the allegation that Distributors conspired to influence DEA production quotas, the claim fails for the additional reason that there is no evidence that Distributors engaged in such conduct.

A. The First Amendment Bars the Claims.

Lobbying and other efforts to influence government action are protected by the First Amendment. The *Noerr–Pennington* doctrine—which derives from *United Mine Workers of America v. Pennington*, 381 U.S. 657 (1965), and *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961)—protects persons from liability for their speech and conduct in exercising their First Amendment right to petition the government. *See Opdyke Inv. Co. v. City of Detroit*, 883 F.2d 1265, 1273 (6th Cir. 1989). “Although the *Noerr–Pennington* doctrine was initially recognized in the antitrust field, the federal courts have by analogy applied it to claims brought under both state and federal laws, including common law claims” *Campbell v. PMI Food Equip. Grp., Inc.*, 509 F.3d 776, 790 (6th Cir. 2007).¹⁹

¹⁸ *Id.* ¶ 897. *See also* Summit TAC ¶¶ 549-50 (alleging that Distributors worked together through the HDA to “influence state and federal governments to pass legislation that supported the use of opioids and limited the authority of law enforcement to rein in illicit or inappropriate prescribing and distribution” and “to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA remained artificially high”).

¹⁹ The doctrine applies regardless of a defendant’s alleged motive. *See, e.g., Noerr*, 365 U.S. at 139 (“The right of the people to inform their representatives in government of their desires with respect to the passage or enforcement of laws cannot properly be made to depend upon their intent in doing so.”); *Lamley v. Bridgestone Firestone, Inc.*, 1992 WL 12666661, at *2 (M.D. Ala. Mar. 31, 1992) (“All persons, regardless of motive, are guaranteed by the First Amendment the right to seek to influence the government or its officials to adopt a new policy, and they cannot be required to compensate another for loss occasioned by a change in policy should they succeed.” (internal quotation marks omitted)).

Where, as here, a defendant's conduct is protected by the First Amendment, a claim for civil conspiracy based on that conduct likewise "must ... fail." *Cinn. Arts Ass'n v. Jones*, 777 N.E.2d 346, 356 (Ohio Ct. Common Pleas 2002). Indeed, the United States Supreme Court's First Amendment precedent mandates this result. *See Snyder v. Phelps*, 562 U.S. 443, 460 (2011) (holding that where allegedly tortious conduct is protected by the First Amendment, a plaintiff "cannot recover for civil conspiracy based on those torts").

Under these settled principles, Plaintiffs' conspiracy claim based on petitioning activity cannot stand. To begin with, *Noerr-Pennington* clearly applies to the conduct Plaintiffs allege. To the extent the claim is based on efforts to persuade legislators "to pass legislation" and "limit[] the authority of law enforcement," *see* Summit TAC ¶ 549, it runs afoul of *Noerr* itself. In that case, the Supreme Court ruled that a publicity campaign designed to "foster the adoption and retention of laws and law enforcement practices" favorable to the defendants, 365 U.S. at 129, could not give rise to liability. The Court held that First Amendment immunity protects "attempts to influence the passage or enforcement of laws," and it is "equally clear" that it "does not prohibit two or more persons from associating together in an attempt to persuade the legislature or executive to take particular action." *Id.* at 135-36.

Similarly, communications intended to influence DEA in setting quotas (had Distributors made such communications, which they did not) would be protected by the *Noerr-Pennington* doctrine. The Supreme Court made clear in *California Motor Transport Co. v. Trucking Unlimited*, that the doctrine also applies to efforts to influence federal and state administrative agencies. 404 U.S. 508, 510-11 (1972). DEA regulations provide that "[t]he Administrator shall determine the total quantity of each basic class of [Schedule I or II] controlled substance ... necessary to be manufactured during the following calendar year." 21 CFR § 1303.11(a). The DEA publishes proposed quotas in the Federal Register, and "any interested person" is permitted

to comment on them. *Id.* 1303.11(c). Thus, if (as Plaintiffs allege) Distributors communicated with DEA about these regulatory functions, that conduct cannot form the basis for liability.²⁰

In short, under settled First Amendment precedent, the Court should reject Plaintiffs' attempt to impose liability on Distributors for allegedly engaging in protected political advocacy. Many courts have dismissed claims like those Plaintiffs assert here. *See, e.g., Tuosto v. Phillip Morris USA*, 2007 WL 2398507, at *5-6 (S.D.N.Y. Aug. 21, 2007) (dismissing fraud claim against cigarette manufacturer in part because the claim was based on allegedly false statements to Congress about the risks of smoking); *Hamilton v. Accu-tek*, 935 F. Supp. 1307, 1321 (E.D.N.Y. 1996) (concluding that lobbying federal officials to prevent handgun regulations cannot form basis of a tort claim in action against handgun manufacturers).²¹

B. Plaintiffs' Conspiracy Claims Based on Alleged Efforts To Influence Quotas Fail for Lack of Evidence.

Plaintiffs have no evidence of a conspiracy to influence the DEA's quota-setting function. Despite months of discovery, no witness—fact or expert—has described any action taken by any Distributor to influence quotas. Plaintiffs hardly bothered even to inquire about quotas in the depositions of Distributors. And, when they did, the witnesses denied any involvement by Distributors.²² The DEA's 30(b)(6) representative testified:

²⁰ Plaintiffs also suggest that statements in an amicus brief the HDMA filed in *Masters*, *see* Summit Compl. ¶ 600, are actionable, but that claim, too, is legally barred because it was subject to an absolute privilege. *See Lisboa v. Lisboa*, 2011 WL 319956, at *4-5 (Ohio Ct. App. Jan. 27, 2011) (affirming dismissal of claim based on allegedly false statements in amicus brief).

²¹ *See also, e.g., McAlonan v. Tracy*, 2011 WL 6125, at *13 (N.J. App. Div. Mar. 16, 2010) (holding that car manufacturer's objections to proposed NHTSA crash-test regulations were "exempt from liability under the Noerr-Pennington doctrine"); *Senart v. Mobay Chem. Corp.*, 597 F. Supp. 502, 506 (D. Minn. 1984) (dismissing claim that was premised on defendant chemical manufacturers' efforts to persuade OSHA to reject proposal for more stringent exposure standards); *Lampley v. Bridgestone Firestone, Inc.*, 1992 WL 12666661, at *1-2 (M.D. Ala. Mar. 31, 1992) (dismissing civil conspiracy claim based on tire companies' alleged conspiracy "to force passage of OSHA regulations" favorable to them); *Cipollone v. Liggett Group*, 668 F. Supp. 408, 410 (D.N.J. 1987) ("furnishing false and misleading information to Congress" about product "entitled to protection as political speech" under *Noerr-Pennington*).

²² *See, e.g., Ex. I.1* (Boggs Tr. (July 19, 2018)) at 97:16-98:21; *Ex. I.22* (Zimmerman Tr. (Feb. 9, 2019)) at 92:4-6.

Q. Now, do wholesale[rs] such as McKesson, Cardinal and AmerisourceBergen provide any information to DEA that is used to set those quotas?

...

A. Quotas are not related to distributors, so no.²³

The public records confirms her testimony. There is a notice-and-comment period before DEA establishes the annual quota, and the Federal Register does not reflect that any Distributor ever commented in favor of increasing opioid quotas.

III. THERE IS NO EVIDENCE THAT DISTRIBUTORS CONSPIRED TO FRAUDULENTLY MARKET OPIOIDS.

The Complaints allege that opioid Manufacturers engaged in a fraudulent marketing scheme to “[c]hange [p]rescriber [h]abits and [p]ublic [p]erception and [i]ncrease [d]emand for [o]pioids” by misrepresenting the clinical risks and benefits of opioids.²⁴ The Complaints more specifically allege that the marketing scheme propagated *nine* falsehoods about the risks and benefits.²⁵ Plaintiffs’ experts may count or categorize the alleged falsehoods differently, but whatever the number and however they are categorized, there is not a shred of evidence that any Distributor knowingly entered into a conspiracy to propagate those alleged falsehoods.

As a threshold matter, Plaintiffs have no evidence that Distributors made claims about the risks and benefits of opioid medications. Not surprisingly, therefore, they have not identified—and cannot identify—a single statement made by a Distributor containing any of the nine falsehoods alleged in the Complaints. Nor is there any evidence that any Distributor knew that the nine alleged statements made by Manufacturers were “false.” To the contrary, Plaintiffs

²³ See Ex. I.9 (Harper-Avilla Tr.) at 111:12-18; 112:9-12; 112:21-113:1.

²⁴ Summit TAC at p. 48; Cuyahoga TAC at p. 46.

²⁵ The alleged falsehoods are: (1) “[t]he risk of addiction from chronic opioid therapy is low”; (2) “[t]o the extent there is a risk of addiction, it can be easily identified and managed”; (3) “[s]igns of addictive behavior are ‘pseudoaddiction,’ requiring more opioids”; (4) “[o]pioid withdrawal can be avoided by tapering”; (5) “[o]pioid doses can be increased without limit of greater risks”; (6) “[l]ong-term opioid use improves functioning”; (7) “[a]lternative forms of pain relief pose greater risks than opioids”; (8) “OxyContin provides twelve hours of pain relief”; and (9) “[n]ew formulations of certain opioids successfully deter abuse.” See Summit TAC at pp. 48-102; Cuyahoga TAC at pp. 46-101.

allege that Manufacturers fooled the entire medical establishment—including the Federation of State Medical Boards, of which the Ohio Medical Board is a member, and DEA, which endorsed the Federation’s guidelines for prescribing opioids—into changing the applicable standard of care.²⁶ Indeed, one of Plaintiffs’ own expert, Dr. David Egilman, opines that Manufacturers “grossly misled distributors” about the risks of addiction.²⁷

None of Plaintiffs’ experts cites evidence that Distributors agreed to disseminate, or did disseminate, any of the nine alleged falsehoods.²⁸ Dr. Egilman and Dr. Matthew Perri identify instances in which certain Distributors provided so-called “marketing” services to manufacturers,²⁹ but the documents they cite show only that those Distributors offered Manufacturers an opportunity to include messages drafted by Manufacturers in various communications, not that any Distributor made promotional statements of its own about the benefits or risks of any drug.³⁰ In this way, Distributors are no different than television networks, radio stations, and magazines that carry pharmaceutical advertisements—parties that

²⁶ See, e.g., Cuyahoga TAC ¶ 362; Summit TAC ¶ 374; Ex. IV.1 (DEA Industry Communicator OxyContin Special (2001), *available at* <https://web.archive.org/web/20011205021713/http://www.deadiversion.usdoj.gov/pubs/nwsltr/spec2001/page10.htm>).

²⁷ Ex. III.1 (Egilman Rep.) B.96. In his scattershot report, which purports to set forth 489 separate opinions, Dr. Egilman also has opined that Distributors joined in a vaguely defined “Venture,” but there is no evidence that any Distributor joined any “Venture” that had an illegal purpose.

²⁸ See Ex. I.10 (Kessler Tr.) at 94:20–21 (“I have no opinions on distributors”); Ex. I.17 (Schumacher Tr.) at 186:5–24 (same); Ex. I.11 (Lembke Tr.) at 274:12–20, 275:7–13 (same); Ex. I.16 (Rosenthal Tr.) at 750:2–6 (same).

²⁹ See Ex. III.5 (Perri Rep.) ¶ 185; Ex. III.1 (Egilman Rep.) B.66, B.85–86, B.109, B.111, B.129, B.135, B.163, B.299, B.430–31, B.482.

³⁰ In the limited instances where Distributors offered opportunities for pharmaceutical manufacturers to include information about their products in communications to pharmacies, that information was drafted by manufacturers, who typically warranted that it complied with all laws. See, e.g., Ex. I.18 (Seid Tr.) at 191:17–20 (Purdue witness testifying that “[Distributors] couldn’t change a comma on what was being sent out.”); Ex. II.5 (MCKMDL00353305) (“The content of the graphical ad is the sole responsibility of Purdue Pharma ... [which] represents and warrants that the graphical ad complies with all applicable laws”); Ex. I.20 (C. Weber Tr. at 58:5–59:7, 61:3–12 (“The material is authored by the supplier, not by AmerisourceBergen.”)); Ex. II.4 (CAH_MDL2804_02958682–83 (“AbbVie shall be fully responsible for the form and content of such e-mail communication as set forth in the Master Services Agreement.”)).

no one would think could be liable for conspiracy with the Manufacturers, even if the messages they transmitted turned out to be misleading.

Moreover, as Dr. Perri acknowledged, these messages transmitted by Distributors “focused generally on price, availability, and other features of interest to pharmacy and other buyers,” not on the risks or benefits of opioid medications.³¹ To the extent these messages included “drug information” at all, it was limited to information drawn from the FDA-approved labeling, which Plaintiffs do not fault.³²

Dr. Perri opines in a conclusory manner that Distributors were involved in marketing simply because distribution “was integral” to the “supply chain” of opioids (and every other drug).³³ But he admitted that distributing needed medications is an “essential service”; that Distributors “do not generate patient level demand;” and that he has no opinion on whether any Distributor acted wrongfully in distributing opioid medications.³⁴ On these facts, the law precludes liability for civil conspiracy—simply placing a product in the chain of distribution is not evidence of joining in Manufacturers’ alleged scheme to mislead the world about the risks of opioids. *See Masepohl v. Am. Tobacco Co., Inc.*, 974 F. Supp. 1245, 1251 (D. Minn. 1997) (holding that conspiracy claim against distributors of cigarettes failed because “[t]he Distributors’ act of placing cigarettes in the chain of distribution cannot possibly be part of an alleged agreement to suppress scientific information regarding the dangers of cigarette smoking[.]” (internal quotation marks omitted)).

³¹ See Ex. III.5 (Perri Rep.) ¶ 185.

³² See Ex. III.5 (Perri Rep.) ¶ 184 n.372 (referring to “information on dosing, kinetics, safety information and patient counseling”).

³³ Ex. III.5 (Perri Rep.) ¶ 184. Even assuming that Distributors had an interest in increasing opioid sales in particular (as opposed to overall sales)—an assumption unsupported by record evidence—selling more of any product is not an illegal objective, and a wholesale distributor’s interest in doing so does not mean that it has conspired with the manufacturer.

³⁴ Ex. I.13 (Perri Tr.) at 212:4–9; 224:19–20; 211:15–21 (“[I]s it right or wrong for a wholesaler to ... sell opioids? You know, that wasn’t ... part of the analysis.”).

Moreover, after extensive discovery, Plaintiffs have failed to find any evidence that Distributors **knowingly** agreed to participate in Manufacturers’ alleged fraud, as is required to establish civil conspiracy. *See, e.g., Williams*, 700 N.E.2d at 868. According to Plaintiffs, Manufacturers concealed their alleged fraud from the broader medical community—including doctors, pharmacies, accrediting agencies, PBMs, and public and private insurers. While Plaintiffs’ theory is that Distributors, unlike those other groups, knew of Manufacturers’ fraud, no **evidence** supports that contention, and it makes no logical sense. The alleged scheme plainly did not require participation by Distributors in order to work—unlike doctors, PBMs and insurance companies, wholesale distributors do not make judgments about medical necessity or whether to pay for any given treatment.

The Ohio Court of Appeals’ decision in *FVI Inc. v. Goodspeed* illustrates the high degree of proof required to make out a knowing agreement for purposes of civil conspiracy. In that case, purchasers of a house sued a mortgage broker who had permitted the seller of the house, a friend of the broker, to perform the appraisal, despite knowing that the seller was on a list of “unapproved” appraisers and had been denied permission to sit for the appraisers exam due to dishonesty. 974 N.E.2d 664, 677 (Ohio Ct. App. 2012). The mortgage broker also entrusted the mortgage-loan documentation process to the seller, contrary to the governing rules. Ultimately, the seller produced a grossly inflated appraisal and reported false information in the loan documentation. Although the court recognized that the broker’s conduct “could be considered negligent or a breach of fiduciary duty,” it held that these facts constituted “neither evidence of malice on the part of [the broker], nor evidence that [the broker] had knowledge of [the seller’s] fraudulent acts.” *Id.* And because there was “no evidence that [the broker] formed an agreement or understanding”—tacit or otherwise—“with [the seller] to harm the [buyers],” the civil conspiracy claim failed. *Id.*; *see also Aetna Cas. & Sur. Co. v. Leahey Const. Co., Inc.*, 219 F.3d

519, 538 (6th Cir. 2000) (reversing civil conspiracy judgment; “the degree of involvement required for civil conspiracy is higher than that for civil aiding and abetting,” because “conspiracy focuses on whether the defendant *agreed to join in* the wrongful conduct” (internal quotation marks omitted)).

The same conclusion applies here, where the alleged misconduct by Distributors is far more attenuated than in *Goodspeed* or *Aetna*. As set forth above, there is no evidence that Distributors made any misrepresentations regarding the risks or benefits of opioid medications. Nor is there any evidence that any Distributor knew that any of the Manufacturer-created messages they may have delivered were misleading or that any Distributor maliciously agreed with Manufacturers to perpetrate a fraud.

IV. THERE IS NO EVIDENCE THAT DISTRIBUTORS CONSPIRED NOT TO REPORT SUSPICIOUS ORDERS.

The Complaints also allege that Distributors entered into a conspiracy not to report suspicious orders. This theory of conspiracy liability apparently encompasses an alleged agreement that each Distributor would not report suspicious orders it received, as well as an alleged agreement not to report suspicious orders received by other distributors.³⁵ As to the first supposed agreement, there is no evidence that any Distributor entered into any such agreement. As to the second, not only does it lack any evidentiary basis, but Distributors had no information about other distributors’ orders on which to base a report in the first place, let alone any legal duty to make reports about other distributors.

³⁵ Cuyahoga TAC ¶¶ 534, 1173; Summit Compl. ¶¶ 551, 1131. To the extent Plaintiffs purport to allege that Distributors conspired with Manufacturers not to report suspicious orders (which is not clearly alleged in the Complaints), that theory would fail for the same lack of evidence discussed in the text.

A. The Claims Relating to a Conspiracy Not To Report Distributors' Own Orders Fail for Lack of Evidence.

There is no triable issue of fact with respect to Plaintiffs' allegation that each Distributor agreed not to report suspicious orders it received. No direct evidence of such an agreement exists, and any purported circumstantial evidence falls far short.

In discovery, Plaintiffs' identified a single email, written by a McKesson employee in 2013, reporting a dinner conversation and attributing to a Cardinal employee a statement that "Cardinal is not reporting suspicious orders to DEA."³⁶ The author of the email has testified under oath that he was mistaken.³⁷ The statement in the email is demonstrably inaccurate: Cardinal reported thousands of suspicious orders in the quarter in which the conversation took place, and even more in the subsequent quarter and for the year 2013.³⁸ But even if the email was accurate—and it was not—there is still nothing indicating *an agreement* among Distributors.

Far from being evidence of an agreement, this email shows the opposite. As to the period before the 2013 conversation, the email proves there was no conspiracy, since the Cardinal employee's purported statement was a "surprising revelation" to McKesson;³⁹ if Cardinal and McKesson had been conspiring not to report orders, the alleged statement would not have been surprising at all. And, as to 2013 forward, the email did not report that the Cardinal employee asked McKesson not to report orders, and the McKesson employee did not state that he agreed to do so. Nor can Plaintiffs cite to any change in either company's conduct following this conversation: to the contrary, Plaintiffs' own expert witnesses point to 2013 as the year when

³⁶ Ex. II.6 (MCKMDL0054341).

³⁷ Ex. I.7 (De Gutierrez-Mahoney Tr.) at 425:12-426:8.

³⁸ Documents produced in discovery, based on data from 39 states, show more than 9,000 reports by Cardinal in the first quarter of 2013 and more than 15,000 reports in the second quarter of 2013. The underlying information was produced at CAH_MDL_PRIORPROD_AG_0009297 - CAH_MDL_PRIORPROD_AG_0009335

³⁹ Ex. II.6 (MCKMDL0054341).

Cardinal and McKesson **began** reporting suspicious orders to DEA.⁴⁰ Under these circumstances, the email does nothing to establish the existence of a conspiracy. *See, e.g., In re Text Messaging Antitrust Litig.*, 782 F.3d 867, 878 (7th Cir. 2015) (rejecting inference of price-fixing conspiracy where meetings between competitors were not followed by “simultaneous or near-simultaneous price increase”).

Even assuming each Distributor failed to make required reports, that would at most indicate independent and parallel conduct, not a conspiracy. Courts reject conspiracy allegations when the circumstantial evidence is “equally consistent with independent conduct.” *See, e.g., Hyland v. HomeServices of Am., Inc.*, 771 F.3d 310, 318–20 (6th Cir. 2014) (internal quotation marks omitted) (affirming judgment dismissing price-fixing conspiracy claim). If each defendant acts in a way that would be in its economic interest only if others agreed to do the same, that may be evidence that they did not act independently but rather conspired with one another. *Id.* But here, Plaintiffs themselves allege that Distributors had an incentive to refrain from reporting suspicious orders, not because of some agreement, but because of “discounts and rebates” purportedly offered by Manufacturers to sell more.⁴¹ Thus, assuming (for purposes of this Motion only) that there was a failure to report by Distributors, the only legally viable inference would be that each Distributor acted independently, not that they reached any conspiratorial agreement.

Plaintiffs’ attempt to manufacture circumstantial evidence by focusing on the Distributors’ trade association, the Healthcare Distribution Alliance (“HDA” or “HDMA”)⁴² also misses the mark. There is no evidence of any unlawful agreement reached through any HDA

⁴⁰ Ex. III.6 (Rafalski Rep.) at 51, 73.

⁴¹ *E.g.*, Cuyahoga TAC ¶ 512; Summit TAC ¶ 528. Plaintiffs misunderstand the operation of the “discounts and rebates,” but, whether or not they operate to encourage Distributors to sell more, that incentive always exists for every seller of every product.

⁴² *See, e.g.*, Cuyahoga TAC ¶ 529; Summit TAC ¶ 545.

meeting, nor any other communication that suggests an agreement not to report suspicious orders. The Complaints allege only vague and facially benign generalities about the HDA, such that it “led to the formation of interpersonal relationships” among Defendants and provided opportunities to “network one on one with manufacturer executives.”⁴³ Those allegations—even if proven—do not make out a conspiracy because they do not establish an agreement to accomplish an unlawful objective. Nor do Plaintiffs’ experts point to any evidence of an unlawful agreement. Dr. Egilman opines in conclusory terms that “HDMA was responsible for sale of unapproved opioids,”⁴⁴ but he cites nothing more than an email in which the trade association passed on to members a clarification it had received from the DEA identifying products that were prohibited from sale. That is not evidence of an agreement not to adhere to that decree or any other legal requirement. Dr. Perri says nothing in his report about HDA and cites only a few documents that show only protected lobbying or again demonstrate that distributors offered to act as a conduit for manufacturers’ informational materials, which, as discussed above, is not probative of any unlawful agreement.

Much of Plaintiffs’ deposition questioning of HDA witnesses focused on the publication (and subsequent withdrawal) of guidelines for suspicious-order monitoring programs. But nothing about those facts bespeaks any sort of conspiratorial agreement. Agreeing (through HDA) to adopt and publish compliance guidelines did not further any unlawful objective. Even assuming that any Distributor failed to follow the guidelines (which were not mandatory), *see* Summit Compl. ¶ 854, there still is no evidence of an agreement or of any unlawful objective. To the extent Plaintiffs contend that Distributors intentionally misled the DEA through the guidelines (*see, e.g., id.* at p. 182, alleging that Distributors “pretend[ed] to cooperate with law enforcement”), that assertion would fail both for lack of evidence of such intent and because any

⁴³ *See, e.g.,* Cuyahoga TAC ¶¶ 518-19; Summit Compl. ¶ 535-36.

⁴⁴ *See* Ex. III.1 (Egilman Rep.) B.100.

alleged efforts to influence the DEA are covered by *Noerr-Pennington* immunity, as explained above. *See supra* Part II.A.

In short, the HDA evidence is legally insufficient to support a conspiracy claim. As the Sixth Circuit has held, attendance at trade association meetings “should not weigh heavily in favor of suspecting collusion.” *In re Travel Agent Comm’n Antitrust Litig.*, 583 F.3d 896, 910–11 (6th Cir. 2009) (affirming dismissal of complaint) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 567 n.12 (2007)).⁴⁵ This is not a novel concept: Almost one hundred years ago the Supreme Court said that “[w]e do not conceive that the members of trade associations become ... conspirators merely because they gather and disseminate information ... bearing on the business in which they are engaged and make use of it in the management and control of their individual businesses.” *Maple Flooring Manu. Ass’n v. United States*, 268 U.S. 563, 584 (1925); *see also N.A.A.C.P. v. Claiborne Hardware Co.*, 458 U.S. 886, 920 (1982) (holding that “[c]ivil liability may not be imposed merely because an individual belonged to a group, some members of which committed [wrongful] acts”).

B. The Claims Relating to a Conspiracy Not To Report Other Distributors’ Orders Fail for Lack of Evidence.

Plaintiffs advance the bizarre and unsupported proposition that each Distributor was required to report suspicious orders received *by other Distributors* from their customers, and that all Distributors entered into a conspiracy not to do so. There is not a bit of evidence to support this supposition. Moreover, as a matter of law, Distributors had no obligation to report

⁴⁵ *See also We, Inc. v. City of Philadelphia*, 174 F.3d 322, 329 (3d Cir. 1999) (“conspiracy liability cannot, consistent with the First Amendment, be imposed based upon mere association”) (citing *N.A.A.C.P. v. Claiborne Hardware Co.*, 458 U.S. 886, 920 (1982)); *Hanson v. Shell Oil Co.*, 541 F.2d 1352, 1359 (9th Cir. 1976) (“[E]vidence of [trade association] meetings alone is not sufficient; there also must be evidence sufficient to permit the jury to infer illegal agreement.”); *In re Asbestos Sch. Litig.*, 46 F.3d 1284, 1287 (3d Cir. 1994) (rejecting argument defendants membership in a trade organization that allegedly disseminated misleading information about asbestos meant that the defendant should be considered part of the civil conspiracy and thus liable); *see also id.* (“A member of a trade group or other similar organization does not necessarily endorse everything done by that organization or its members.”).

suspicious orders they did not themselves receive. Nothing in either the CSA or the DEA's regulations even suggests such an obligation. The DEA itself agrees there is no such duty:

Q. The CSA does not require distributors to report the suspicious orders of other distributors, does it?

A. Correct.

...

Q. Now, similarly, the regulations do not require distributors to report suspicious orders of other distributors, correct?

A. Correct.⁴⁶

As a practical matter, a Distributor does not have the ability to monitor the orders that a pharmacy or other customer places with a competitor, let alone to monitor the orders placed by any party that is not the distributor's customer. In some instances, customers permitted a distributor to have access—either periodically or monthly—to information indicating the volume of products they *dispense*. But dispensing data shows only the volume of products dispensed to consumers; it does not provide a Distributor the “size,” “pattern,” or “frequency” of particular orders placed by a buyer with another distributor. 21 C.F.R. § 1301.74(b). And even if a Distributor had access to product volume received by a pharmacy from another distributor(s), there is no evidence that the first distributor would see specific orders; would know if the other distributor(s) had reported any orders as suspicious; would know if the other distributor(s) had held or declined to fill any orders; or would know the identities of prescribing doctors or other contextual information bearing on whether any order is suspicious. There is simply no way a Distributor could report anything to the DEA about other distributors' orders.

At bottom, Plaintiffs seek to bootstrap their allegation that Distributors did not report each other's allegedly suspicious orders into an inference that they *agreed* not to report each other's orders. But as the Sixth Circuit has made clear, even where (unlike here) failure to report

⁴⁶ Ex. I.14 (Prevoznik Tr.) at 261:1–4, 10–14.

another person's wrongdoing is itself unlawful, that failure does not amount to proof of a conspiracy. *See Castaneda De Esper v. Immig. & Nat. Serv.*, 557 F.2d 79, 84 (6th Cir. 1977) ("Misprision is not conspiracy."). Here, too, the absence of evidence of an agreement is fatal to Plaintiffs' conspiracy claim.

CONCLUSION

For the reasons stated above, the Court should grant summary judgment dismissing the conspiracy claims as to the Distributors.

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Respectfully Submitted,

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LOCAL RULE 7.1(F) CERTIFICATION

Pursuant to the Court's Order Regarding Pretrial Motions for "Track One" Trial, ECF # 1653, Defendants have 60 pages collectively for joint summary judgment motions regarding conspiracy. This brief adheres to the limits set forth in that order, as it totals 20 pages.

/s/ Ashley W. Hardin
Ashley W. Hardin

CERTIFICATE OF SERVICE

I, Ashley W. Hardin, hereby certify that the foregoing document as served via the Court's ECF system to all counsel of record.

/s/ Ashley W. Hardin
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